07-cv-5574
STANTON

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

SUMMARY ORDER

RULINGS BY SUMMARY ORDER DO NOT HAVE PRECEDENTIAL EFFECT. CITATION TO SUMMARY ORDERS FILED AFTER JANUARY 1, 2007, IS PERMITTED AND IS GOVERNED BY THIS COURT'S LOCAL RULE 32.1 AND FEDERAL RULE OF APPELLATE PROCEDURE 32.1. IN A BRIEF OR OTHER PAPER IN WHICH A LITIGANT CITES A SUMMARY ORDER, IN EACH PARAGRAPH IN WHICH A CITATION APPEARS, AT LEAST ONE CITATION MUST EITHER BE TO THE FEDERAL APPENDIX OR BE ACCOMPANIED BY THE NOTATION: "(SUMMARY ORDER)." A PARTY CITING A SUMMARY ORDER MUST SERVE A COPY OF THAT SUMMARY ORDER TOGETHER WITH THE PAPER IN WHICH THE SUMMARY ORDER IS CITED ON ANY PARTY NOT REPRESENTED BY COUNSEL UNLESS THE SUMMARY ORDER IS AVAILABLE IN AN ELECTRONIC DATABASE WHICH IS PUBLICLY ACCESSIBLE WITHOUT PAYMENT OF FEE (SUCH AS THE DATABASE AVAILABLE AT HTTP://WWW.CA2.USCOURTS.GOV/). IF NO COPY IS SERVED BY REASON OF THE AVAILABILITY OF THE ORDER ON SUCH A DATABASE, THE CITATION MUST INCLUDE REFERENCE TO THAT DATABASE AND THE DOCKET NUMBER OF THE CASE IN WHICH THE ORDER WAS ENTERED.

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Daniel Patrick Moynihan United States Courthouse, 500 Pearl Street, in the City of New York, on the 24th day of August, two thousand nine.

PRESENT: JOSEPH M. McLAUGHLIN,
GUIDO CALABRESI,
REENA RAGGI,
Circuit Judges,

AVON PENSION FUND, ADMINISTERED BY BATH & NORTH EAST SOMERSET COUNCIL AND NORTH YORKSHIRE COUNTY COUNCIL, ADMINISTERING AUTHORITY FOR THE NORTH YORKSHIRE PENSION FUND, PLUMBERS & STEAMFITTERS LOCAL 773, and PLUMBERS' UNION LOCAL NO. 12,

Plaintiffs-Appellants,

LEON D. BOROCHOFF, on behalf of himself and all others similarly situated,

Plaintiff,

No. 08-4363-cv

v.

GLAXOSMITHKLINE PLC, DR. JEAN-PIERRE GARNIER, JULIAN HESLOP, SIMON BICKNELL, and DAVID STOUT,

Defendants-Appellees.

APPEARING FOR APPELLANTS: JOSEPH D. DALEY, Coughlin Stoia Geller Rudman & Robbins LLP, San Diego, California (Samuel H. Rudman and David A. Rosenfeld, Coughlin Stoia Geller Rudman & Robbins LLP, Melville, New York, *on the brief*).

APPEARING FOR APPELLEES: ROBERT L. HICKOK, Pepper Hamilton LLP, Philadelphia, Pennsylvania (Gay Parks Rainville and Michael E. Baughman, Pepper Hamilton LLP, Philadelphia, Pennsylvania; Kenneth J. King, Pepper Hamilton LLP, New York, New York, *on the brief*).

Appeal from the United States District Court for the Southern District of New York (Louis L. Stanton, Judge).

UPON DUE CONSIDERATION, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the judgment of the district court entered on May 13, 2008, is AFFIRMED.

Plaintiffs sued defendants GlaxoSmithKline PLC ("GSK"), Dr. Jean-Pierre Garnier, Julian Heslop, Simon Bicknell, and David Stout for securities fraud under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 for non-disclosure of alleged cardiovascular risks associated with the drug Avandia. They now appeal the dismissal of their complaint pursuant to Rule 12(b)(6), a ruling we review de novo, accepting all allegations in the complaint as true and drawing all reasonable inferences in favor of plaintiffs. See Vietnam Ass'n for Victims of Agent Orange v. Dow Chem. Co., 517 F.3d 104, 115 (2d Cir. 2008); accord Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949-50 (2009). Alternatively, plaintiffs appeal the denial of leave to amend the complaint, which we review for abuse of discretion. See Burch v. Pioneer Credit Recovery, Inc., 551 F.3d 122, 126 (2d

Cir. 2008). We assume the parties' familiarity with the facts and record of prior proceedings, which we reference only as necessary to explain our decision to affirm.

1. Grant of Defendants' Motion to Dismiss

Plaintiffs contend that the district court erred in concluding that (a) the potential risks of Avandia reported in two meta-analyses were not sufficiently conclusive to create a duty to disclose, and (b) the complaint failed to plead facts with the particularity necessary to support an inference of the requisite scienter. We address these challenges in turn.

a. The Non-disclosed Meta-Analyses

Reports or test results must yield reliable evidence of a drug's adverse effect to give rise to a duty of manufacturers to disclose those results to potential investors. See In re Carter-Wallace, Inc. Sec. Litig., 150 F.3d 153, 157 (2d Cir. 1998). While the complaint conclusorily alleges that the results of the meta-analyses "showed an estimate" of an "increased risk of heart attack," Compl. ¶¶ 25, 26, it pleads no facts indicating that the test results were even statistically significant. In fact, the complaint incorporates by reference the 2007 congressional testimony of Commissioner Andrew von Eschenbach, M.D., of the Food and Drug Administration stating that the meta-analyses here at issue "presented inconsistent data with regard to the potential cardiovascular risk" of Avandia and that "[i]n looking at all the studies to date . . . , the data are inconsistent and conclusions are not clear." Joint App. at 375; see Compl. ¶ 27; Mangiafico v. Blumenthal, 471 F.3d 391, 398 (2d Cir. 2006). Because any alleged non-disclosure of such inconclusive results cannot be deemed

misleading or material, the district court correctly concluded that plaintiffs could not pursue an action for failure to disclose. See Basic Inc. v. Levinson, 485 U.S. 224, 239 n.17 (1988) ("To be actionable, . . . a statement must also be misleading. Silence, absent a duty to disclose, is not misleading under Rule 10b-5."); Vacold LLC v. Cerami, 545 F.3d 114, 121 (2d Cir. 2008).

b. Scienter

Plaintiffs concede that "no single allegation proves that during the Class Period defendants knew that their statements (and omissions) concerning Avandia were false or misleading." Appellants' Br. at 55. Nevertheless, they argue that the allegations in the complaint, when "viewed in combination, support a strong inference that defendants knew their statements and omissions were false and misleading." Id. at 46. These allegations include the "myriad findings of statistical significance" in various studies conducted by GSK, id. at 48; the "sheer importance of Avandia to [GSK's] bottom line," id. at 50; the timing of the alleged misstatements with the disclosure in a March 2007 article written by an independent physician that Avandia posed cardiovascular risks; and seven GSK insiders' sale of their shares during the class period.

On a Rule 12(b)(6) motion, a court properly considers "whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." Tellabs, Inc.v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322-23 (2007) (emphasis in original). "[T]he inference

of scienter must be more than merely 'reasonable' or 'permissible' – it must be cogent and compelling." Id. at 324; accord ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 99 (2d Cir. 2007). Upon de novo review, we conclude that "all of the facts alleged" in the complaint are insufficient to raise a cogent and compelling inference of defendants' "intent to deceive, manipulate, or defraud." Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.7 (1976); see 15 U.S.C. § 78u-4(b)(2); see also ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d at 99 n.3.

First, the allegations of insider trading do not show defendants' motive to defraud. Cf. Kalnit v. Eichler, 264 F.3d 131, 138 (2d Cir. 2001) ("A plaintiff can establish [fraudulent] intent . . . by alleging facts to show that defendants had both motive and opportunity to commit fraud." (internal quotation marks omitted)). While "unusual insider trading activity during the class period may permit an inference of bad faith and scienter," Acito v. IMCERA Group, Inc., 47 F.3d 47, 54 (2d Cir. 1995), the individual defendants' trading activities were hardly unusual. Three of the four individual defendants increased their net holdings of GSK stock during the class period, and the fourth individual defendant did not sell any shares at all. This trading history cannot support a "cogent and compelling" inference of fraudulent intent; rather, defendants' purchases of even more GSK stock during the relevant period signals only confidence in the future of their company and, by extension, in the commercial success of Avandia. See Tellabs, Inc., 551 U.S. at 324.

Second, plaintiffs' circumstantial pleadings, even when considered in the aggregate,

do not permit an inference of defendants' "conscious misbehavior or recklessness." Kalnit v. Eichler, 264 F.3d at 142 ("Where motive is not apparent, it is still possible to plead scienter by identifying circumstances indicating conscious behavior by the defendant, though the strength of the circumstantial allegations must be correspondingly greater." (internal quotation marks omitted)). In the face of contradictory studies, the fact that Avandia was one of GSK's "key growth products," Appellants' Br. at 50, and the fact that only a few months separated the purportedly misleading statements and the 2007 article, are insufficient to plead defendants' conscious or reckless neglect in not disclosing the results of the meta-analyses to investors.[1] Indeed, like the district court, we conclude that GSK's disclosure of the meta-analyses results to the FDA and its publication of this information on its website effectively refutes plaintiffs' claim that the pleaded circumstances support the requisite scienter. See Borochoff v. GlaxoSmithKline PLC, 2008 WL 2073421, at *8. Accordingly, plaintiffs' securities fraud claim was properly dismissed.

2. Denial of Plaintiffs' Request to Amend Complaint

Plaintiffs claim that the district court abused its discretion in denying leave to amend the complaint. Although the decision of whether to allow amendment "is left to the sound

[1] Nor may plaintiffs rely on defendant David Stout's statements in an investor conference call that test results for the drug "exceeded everyone's expectations, in some cases even our own, where we beat metformin on performance and we tied them on the cardiovascular safety." Compl. ¶ 60. While Stout may have had a duty to disclose the unfavorable meta-analyses "in order to make the statements made, in light of the circumstances under which they were made, not misleading," 17 C.F.R. § 10b-5(b), that, by itself, is insufficient to support a strong inference of scienter.

discretion of the district court, there must be good reason to deny the motion." Acito v. IMCERA Group, Inc., 47 F.3d at 55. One such reason is futility. See id. Upon review of plaintiffs' proposed supplemental pleadings, the district court determined that they would not cure the identified defects in the complaint. We agree.

To satisfy the scienter requirement, plaintiffs proposed to amend their complaint to plead: (1) the results of meta-analyses conducted by GSK and another independent scientist; (2) additional evidence of economic loss; (3) defendants' alleged 1999 intimidation of Dr. John Buse, an independent scientist, to prevent him from publicly speaking about his concerns with Avandia; and (4) a 2008 FDA warning letter citing GSK's failure to provide a complete report of clinical data related to Avandia. The first two allegations add nothing to similar pleadings in the original complaint. As for the allegation pertaining to Dr. Buse, *we cannot conclude that the district court abused its discretion in denying leave to amend to* add this pleading in light of the doctor's acknowledgment that GSK individuals "felt that they were trying to be forthright in presenting the data with regard to their drug," which belies an intent to conceal information. Appellees' Br. at 53 (citing Buse statement and testimony before Congress in 2007[2]). Finally, the FDA warning letter – either on its own or considered with the other allegations – does not support an inference of the requisite scienter.

[2] Although the transcript of Dr. Buse's statement and testimony are not attached to the proposed amended complaint, they may nevertheless be considered in ruling on a Rule 12(b)(6) motion as they are incorporated by reference. See Mangiafico v. Blumenthal, 471 F.3d at 398.

The letter indicates that some of GSK's reports to the agency were incomplete, but it acknowledges that several studies not included in the reports were otherwise disclosed in other notifications to the FDA. See FDA, Warning Letter to GlaxoSmithKline (Mar. 25, 2008), available at www.fda.gov (follow "Recalls & Alerts - Warning Letters" hyperlink). While the letter does indicate reporting failures, it does not suggest that such lapses were motivated by an intent to deceive. See Acito v. IMCERA Group, Inc., 47 F.3d at 55 (holding that FDA's warning of potential penalties if plant fails third inspection does not support inference of scienter as a matter of law because "mismanagement alone does not constitute fraud").

We have considered plaintiffs' other arguments on appeal and conclude that they are without merit. Accordingly, we AFFIRM the judgment of the district court.

FOR THE COURT:
CATHERINE O'HAGAN WOLFE, Clerk of Court

By: _____

A TRUE COPY
Catherine O'Hagan Wolfe, Clerk
by _____
DEPUTY CLERK